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K131913

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this Premarket Notification is:

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This summary was prepared on October 25, 2013.

2. The names of the devices are:

Trade names: IntelliVue CL SpO2 Pod and CL NBP Pod
Common name: Telemetry Transceiver

Trade names: Philips IntelliVue Patient Monitors MP5, MP5T, MP5SC
Common name: Multiparameter Patient Monitors

Classification of the IntelliVue CL SpO2 Pod and CL NBP Pod

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and Alarm, Arrhythmia
	§870.1100, II	DSJ	Alarm, Blood-Pressure
	§870.1110, II	DSK	Computer, Blood-Pressure
	§870.1120, II	DXQ	Cuff, Blood-Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.2030, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2700, II	DQA	Oximeter
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
	-	MSX	System, Network and Communication, Physiological Monitors

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Classification of the IntelliVue Patient Monitors MP5, MP5T, and MP5SC:

Device Panel	Classification	ProCode	Description
	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2700, II	DQA	Oximeter
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)

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Device Panel	Classification	ProCode	Description
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
	§880.2910, II	FLL	Thermometer, Electronic, Clinical

3. The modified Philips IntelliVue CL SpO2 Pod and CL NBP Pod, software Rev. B.02, are substantially equivalent to the previously cleared IntelliVue CL SpO2 Pod and CL NBP Pod marketed pursuant to K101600 and K111905. With respect to the local attended monitoring feature the modified IntelliVue CL SpO2 Pod and CL NBP Pod are substantially equivalent to the Philips IntelliVue X2 Multi-Measurement Module software Rev. J.07 marketed pursuant to K122223, K122439, K120366, K113441, K113657, K110622, K102562, K083517, K082633, K072070, and K071426.

The new Philips air hose Mobile CL Air Hose-Bayonet Connector is substantially equivalent to the previously cleared Philips air hoses Mobile CL Extension Air Hose marketed pursuant to K101600 and M1598B marketed pursuant to K052707.

The modified Philips IntelliVue Patient Monitors MP5, MP5T, and MP5SC, software Rev. J.20, are substantially equivalent to the previously cleared IntelliVue Patient Monitors MP5, MP5T, and MP5SC marketed pursuant to K122439, K122223, K120366, K113657, K113441, K110622, K102562, K091395, K083517, K083228, K082633, K081793, K071426, K063725, and K062392.

4. Description of the devices

The IntelliVue CL SpO2 Pod is a small, battery powered, wrist worn pulse oximeter device for cableless monitoring of patients. It contains Philips FAST-SpO2 (Fourier Artifact Suppression Technology) to provide reliable saturation values under various artifact conditions including motion and low perfusion.
It uses a measurement principle that is based on the specific absorption characteristics of oxyhemoglobin and deoxyhemoglobin and the pulsating arteriolar vascular bed at the measurement site. It provides continuous operating mode and intermittent operating mode with configurable measurement intervals. The integrated monochrome LCD display shows measured values, measurement signal quality, battery state, and RF signal strength. It communicates measurement values and other information to an IntelliVue Patient Monitor or an IntelliVue Information Center via a telemetry device. It also acquires SpO2 and pulse rate

data for a clinical information management system. It has three hardkeys for basic operation and navigation. It supports specialized Philips reusable and disposable SpO2 sensors.

The IntelliVue CL NBP Pod is a small, battery powered, non-invasive blood pressure and pulse rate measurement device for cableless monitoring of patients. It uses oscillometric method for measuring NBP. It produces numerics for systolic, diastolic and mean blood pressure values and pulse rate. The integrated monochrome LCD Display shows measured values, battery state, and RF signal strength. It communicates measurement values and other information to an IntelliVue Patient Monitor or an IntelliVue Information Center via a telemetry device. It also acquires systolic, diastolic, and mean pressure and pulse rate data for a clinical information management system. It has three hardkeys for basic operation and navigation. It supports specialized Philips reusable and disposable NBP cuffs and air hoses. Both measuring devices the CL SpO2 Pod and the CL NBP Pod can also be controlled from an assigned IntelliVue Patient Monitor, an IntelliVue Information Center via a telemetry device, or from the IntelliVue GuardianSoftware via the hospital IT infrastructure. They communicate with the compatible devices using a wireless Short Range Radio (SRR) interface in the 2.4 GHz ISM frequency band.

The modification to the IntelliVue CL SpO2 Pod and CL NBP Pod enables local physiological alarm indication on these devices for local attended monitoring without a host patient monitor, e.g. during in-hospital transport attended by a care giver. This notifies clinical personnel about possibly threatening situations for a patient.

The modification to the IntelliVue CL SpO2 Pod introduces pulse tone and pulse tone modulation locally at the IntelliVue CL SpO2 Pod to allow clinical personnel to hear deviations of the patients pulse frequency and saturation levels also during local attended monitoring (without a patient monitor).

The IntelliVue CL NBP Pod has additionally been modified in order to enhance accuracy of diastole and Mean Arterial Pressure (MAP) measurements in order to enhance the margin to the limits specified in the recognized consensus standards ANSI/AAMI SP10 and ISO 81060-2.

To supplement the range of measurement accessories, the CL NBP Pod has also been validated for use with a series of additional, legally marketed Philips cuffs.
To connect the additional Philips cuffs a new adapter hose, the Mobile CL Air Hose-Bayonet Connector (model No.: 989803187431), has been setup and added to the list of accessories. As the legally marketed Philips Mobile CL Extension Air Hose, the new hose is explicitly intended for use with the IntelliVue CL NBP Pod.

The IntelliVue Patient Monitors MP5, MP5T, and MP5SC consist of 8.4" TFT LCD display unit including built-in central processing unit (CPU) and multiple physiological measurements. All monitor models share the same architecture of CPU units and the same software is executed on each monitor. They are robust, portable, lightweight, compact in size and modular in design, with interfaces to dedicated external measurement devices. The MP5, MP5T and MP5SC monitors have varying measurement sets and network capabilities. All

models can be used with adult, pediatric and neonatal patients in a hospital and transport environment. They store data in trend, event, and calculation databases. Tabular trends (vital signs) can be watched on display and documented on a printer.
The MP5 monitor provides a comprehensive set of basic physiological measurements: NBP, SpO2, and optionally ECG, invasive blood pressure, predictive temperature, standard temperature and CO2. Through networking it provides information integration, documentation and information access.
The MP5T monitor is intended for use together with a telemetry device. It has no ECG measurement of its own but does have NBP and optionally SpO2 and predictive temperature. When the telemetry device is directly connected to the MP5T, the measurements from the MP5T are transmitted with those from the telemetry device (ECG and optionally SpO2) to the Information Center.
The MP5SC monitor is customized for use as a multi-patient spot check monitor. It has SpO2 and NBP and optionally predictive temperature or Microstream CO2. A telemetry device can be connected via short range radio (SRR) to the MP5SC to provide an ECG measurement.

When used together with the IntelliVue CL SpO2 Pod and CL NBP Pod, the MP5, MP5T, and MP5SC monitors receive via Short Range Radio (SRR) interface measurement values. The measurement data is displayed and recorded on the patient monitors. The patient monitors also receive technical and physiological alarms generated in the CL SpO2 and NBP Pods for their audible and visual indication on the monitors. In addition, the patient monitors can control some functions of the CL SpO2 and NBP Pods via SRR link.

The common software of the IntelliVue Patient Monitors MP5, MP5T, and MP5SC has slightly been modified to allow the operator to start and to end local attended monitoring of the IntelliVue CL SpO2 Pod and CL NBP Pod.

5. Intended Use

IntelliVue CL SpO2 Pod:

The IntelliVue CL SpO_2 Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters SpO_2 and pulse rate wirelessly.
The intended use of the IntelliVue CL SpO_2 Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring, and recording of, and to generate alarms for, arterial oxygen saturation and pulse rate of adult and pediatric patients.
The IntelliVue CL SpO_2 Pod is also intended for local attended monitoring of, and to generate alarms for, arterial oxygen saturation and pulse rate of adult and pediatric patients.
The IntelliVue CL SpO_2 Pod is also intended for acquisition of arterial oxygen saturation and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL SpO_2 Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

Local Attended monitoring refers to situations where clinical staff is close to the patient such that acoustic alarming of the IntelliVue CL SpO_2 Pod will be noticed. Example: In-hospital transport of a patient by hospital staff to a procedure room.

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IntelliVue CL NBP Pod:

The IntelliVue CL NBP Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters non-invasive blood pressure and pulse rate wirelessly.
The intended use of the IntelliVue CL NBP Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring and recording of, and to generate alarms for, systolic, diastolic, and mean pressure, and to measure pulse rate of adult and pediatric patients.
The IntelliVue CL NBP Pod is also intended for local attended monitoring of, and to generate alarms for, systolic, diastolic, and mean pressure, and to measure pulse rate of adult and pediatric patients.
The IntelliVue CL NBP Pod is also intended for acquisition of systolic, diastolic, and mean pressure and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL NBP Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

Local Attended monitoring refers to situations where clinical staff is close to the patient such that acoustic alarming of the IntelliVue CL NBP Pod will be noticed. Example: In-hospital transport of a patient by hospital staff to a procedure room.

IntelliVue Patient Monitors MP5, MP5T, and MP5SC:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.

The MP5, MP5SC and MP5T monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5, MP5SC and MP5T when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMIEC11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.

The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

6. Technological Characteristics

The modifications to the IntelliVue CL SpO2 Pod and CL NBP Pod and the Patient Monitors MP5, MP5T, and MP5SC do not affect their technological characteristics. Design, materials, energy source, portability, user interface, radio technology, measurement principle, and performance specifications of the devices remain all unchanged as they are.

This new adapter hose Mobile CL Air Hose-Bayonet Connector is based on the design and components from two legally marketed Philips air hoses: Mobile CL Extension Air Hose, model No.: 989803163131 (tubing and plastic male connector) and air hose model No.: M1598B (metal bayonet connector). The new Mobile CL Air Hose-Bayonet Connector has the same dimensions and environmental specifications as the legally marketed Mobile CL Extension Air Hose. Biocompatibility is ensured through the reuse of components from the predicate hoses, which are made of the same materials.

7. Summary of V&V activities

- Non-Clinical Performance Tests (bench testing):

The measurement ranges of systolic, diastolic and mean arterial pressure of the modified IntelliVue CL NBP Pod were validated by means of comparison with the legally marketed predicate IntelliVue CL NBP Pod by way of a series of several hundred paired measurements on a blood pressure simulator with blood pressure values covering the specified measurement range.
The comparative testing has demonstrated that the modified IntelliVue CL NBP Pod has produced over the specified measurement range systolic, diastolic and mean arterial pressure measurement results equivalent to those of the legally marketed predicate IntelliVue CL NBP Pod.

Performance of the new hose Mobile CL Air Hose – Bayonet Connector with respect to durability, cleaning and disinfection was validated according to the same methods and pass/fail criteria as the predicate hose. The performed tests demonstrate that the new hose is resistant against the specified disinfectants, does meet its reliability and performance specifications and its performance is equivalent to that of the predicate hose.

- Clinical Performance Tests

The overall efficacy of the modified IntelliVue CL NBP Pod in combination with its specialized legally marketed accessories and with the new Mobile CL Air Hose-Bayonet

Connector together with additional legally marketed Philips cuffs was clinically validated according to the ANSI/AAMI SP10 and ANSI/AAMI/ISO 81060-2 standards.

The modified IntelliVue CL NBP Pod met all safety and efficiency requirements and demonstrated that the accuracy requirements (measured by means of mean error and standard deviations, using the same Arm Sequential Method - Dual Observer - in Comparison to a Mercury Reference Sphygmomanometer) for the number of subjects, number of paired measurements, age distribution, gender distribution, arm circumference distribution, and blood pressure distribution requested in both standards were met.

An additional clinical validation was done following requirements of section 5.2.6 Ambulatory monitoring method of ISO 81060-2:2013 standard. The modified IntelliVue CL NBP Pod met all safety and efficiency requirements and demonstrated that the accuracy requirements (measured by means of mean error and standard deviations, using opposite arm simultaneous method - Dual Observer - in comparison to a Mercury Reference Sphygmomanometer) requested in this section of the standard were met.

- Clinical Usability Testing to evaluate acceptance (ease of use) and clinical usefulness of the implementation of local alarming in the IntelliVue CL SpO2 and CL NBP Pod and pulse tone modulation in the CL SpO2 Pod.
  All defined pass criteria have been met.

- Testing according to the following recognized consensus standards:
  - IEC 62304:2006 (Software life cycle processes)
  - IEC 60601-1-8:2003 (Alarms)
  - ISO 9919:2005 (Pulse Oximeter)
  - ANSI/AAMI SP10:2002/(R)2008 & ANSI/AAMI SP10:2002/A1:2003/(R)2008 & ANSI/AAMI SP10:2002/A2:2006/(R)2008 and ANSI/AAMI/ISO 81060-2:2009 (Non-invasive sphygmomanometers)

  All applicable requirements have been met.

- Testing as identified in the Hazard Analysis. All specified pass/fail criteria have been met. The test results have confirmed the effectiveness of implemented design risk mitigation measures.

- Function testing on the modified IntelliVue CL SpO2 Pod, CL NBP Pod and Patient Monitors MP5, MP5T, MP5SC.
  All specified criteria have been met. The test results have confirmed that all modified devices have functioned safe, effective and according to the specifications and Instructions for Use in the intended environment of use.

- Regression testing of the related, unchanged software parts of the IntelliVue CL SpO2 Pod, CL NBP Pod and Patient Monitors MP5, MP5T, MP5SC. All specified criteria have been met. The test results have confirmed that all modified devices have functioned safe, effective and according to the specifications and Instructions for Use in the intended environment of use.

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8. Conclusion

Verification and validation testing activities were conducted to establish the performance, safety, functionality, usability, effectiveness, and reliability characteristics of the modified devices. V&V testing included clinical and bench performance tests, clinical usability, function, and regression tests. All clinical and non-clinical tests were successfully completed.

The results demonstrate that the modified Philips IntelliVue CL SpO2 Pod, CL NBP Pod and Patient Monitors MP5, MP5T, MP5SC are as safe, as effective and perform as well as the predicate devices.

The modified devices are substantially equivalent in intended use and fundamental technological characteristics to the appropriate predicate devices. The devices introduce no new questions concerning the safety or efficacy and are, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Philips Medizin Systeme Boeblingen Gmbh
Markus Stacha
Hewlett-packard Str. 2
Boeblingen, Bw, D-71034 GM

Re: K131913
Trade/Device Name: Intellivue Cl SPO2 Pod and CL NBP Pod, Philips Intellivue Patient Monitors MP5, MP5T, MP5SC
Regulation Number: 21 CFR 870.2700
Regulation Name: Telemetry Transceiver, Multiparameter Patient Monitors
Regulatory Class: Class II
Product Code: DRG, DXJ, MSX, DSI, DSK, DSJ, DXQ, DSA, DXG, DRT, DRQ, DQA, DXN
Dated: October 25, 2013
Received: October 31, 2013

Dear Markus Stacha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name:

- Philips IntelliVue CL SpO2 Pod
- Philips IntelliVue CL NBP Pod
- Philips IntelliVue Patient Monitors MP5, MP5T, MP5SC

Indications for Use:

IntelliVue CL SpO2 Pod:

The IntelliVue CL SpO_2 Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters SpO_2 and pulse rate wirelessly.

The intended use of the IntelliVue CL SpO_2 Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring, and recording of, and to generate alarms for, arterial oxygen saturation and pulse rate of adult and pediatric patients.

The IntelliVue CL SpO_2 Pod is also intended for local attended monitoring of, and to generate alarms for, arterial oxygen saturation and pulse rate of adult and pediatric patients.

The IntelliVue CL SpO_2 Pod is also intended for acquisition of arterial oxygen saturation and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL SpO_2 Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

Local attended monitoring refers to situations where clinical staff is close to the patient such that acoustic alarming of the IntelliVue CL SpO_2 Pod will be noticed. Example: In-hospital transport of a patient by hospital staff to a procedure room.

Continued on next pages

Prescription Use __Yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.11.26 14:16:31 -05'00'

Indications for Use (continued):

IntelliVue CL NBP Pod:

The IntelliVue CL NBP Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters non-invasive blood pressure and pulse rate wirelessly.

The intended use of the IntelliVue CL NBP Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring and recording of, and to generate alarms for, systolic, diastolic, and mean pressure, and to measure pulse rate of adult and pediatric patients.

The IntelliVue CL NBP Pod is also intended for local attended monitoring of, and to generate alarms for, systolic, diastolic, and mean pressure, and to measure pulse rate of adult and pediatric patients.

The IntelliVue CL NBP Pod is also intended for acquisition of systolic, diastolic, and mean pressure and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL NBP Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

Local attended monitoring refers to situations where clinical staff is close to the patient such that acoustic alarming of the IntelliVue CL NBP Pod will be noticed. Example: In-hospital transport of a patient by hospital staff to a procedure room.

IntelliVue Patient Monitors MP5, MP5T, and MP5SC:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.

The MP5, MP5SC and MP5T monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5, MP5SC and MP5T when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

Continued on next page

Indications for Use (continued):

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMIEC11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.